Supreme Court, U.S.
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No. 91-685

IN THE

Supreme Court of the United States

OCTOBER TERM, 1991

LEDERLE LABORATORIES, Division Of American Cyanamid Company,

Petitioner,

v.

CAROL ANN FELDMAN,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF NEW JERSEY

REPLY BRIEF IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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We showed in our petition that (1) the New Jersey Supreme Court's decision on important questions of preemption law conflicts with the decisions of two federal courts of appeals, and (2) the state court erred in holding that petitioner could be liable for failing to satisfy a "duty to warn" under state tort law when, at the same time, federal law expressly barred the use of warnings not approved by the Food and Drug Administration ("FDA") *and* the FDA had specifically declined to approve the warning at issue. In opposition to the petition, respondent concedes the first point[1] and virtually ignores the second.

Federal law required the FDA's prior approval of any warning before petitioner could place it on its Declomycin® "label" (a term broadly defined to include other descriptive materials accompanying the distribution of a drug).[2] The state-imposed "duty to

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[1] We argued that the New Jersey Supreme Court's decision in this case conflicts with *Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 851 F.2d 1536, *modified*, 863 F.2d 1173 (5th Cir. 1988) (Pet. at 9-10), and *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir.), *petition for cert. filed*, 59 U.S.L.W. 3825 (U.S. May 29, 1991) (No. 90-1837) (Pet. at 10-11). Respondent does not contend that *Hurley* and *Papas* are not in conflict with the state court's decision in this case; she merely argues that they are incorrect and should be ignored. Brief in Opp. 12-13.

[2] Contrary to respondent's assertions, Brief in Opp. 14, subsequent changes in federal drug labeling regulations are irrelevant to this case. The question in this case is whether petitioner can be held liable under state law for failing to give a warning barred by federal law; later changes in the federal law do not affect the analysis or the importance of that question, which recurs under a variety of contemporary statutory schemes (as the *Hurley* and *Papas* cases demonstrate). *See* Pet. 3-4 and n.1.

warn," on the other hand, requires drug manufacturers to provide warnings of known or knowable risks, whether FDA has approved or, as here, specifically disapproved such warnings. Petitioner could satisfy the state law duty to warn only by violating the federally imposed duty to use only those warnings that had received FDA approval. In such a situation, federal law must prevail.

In opposing the petition, respondent provides a long dissertation on federal preemption doctrine and argues that FDA's labeling regulations can have no preemptive force because federal law does not expressly provide a private remedy for injuries resulting from the failure to provide warnings. Congress, respondent claims, would not have abrogated a state remedy without explicitly saying that it was doing so, unless it provided a substitute federal remedy. Brief in Opp. 10-12. (This argument also is being made in *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541 (3d Cir. 1990), *cert. granted*, 111 S. Ct. 1386 (1991), *argued*, 60 U.S.L.W. 3278 (Oct. 8, 1991), *restored to calendar for reargument*, Order List (Oct. 21, 1991), and, for this reason alone, the writ should be granted

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Moreover, even though pre-approval of new warnings is no longer required for drugs as a general matter, *but cf. Hurley*, 863 F.2d at 1179 (prior FDA approval is required for warnings given with biologics), current law does not permit a drug manufacturer like petitioner to ignore a determination by FDA that a proposed warning would be inappropriate. *See* 21 C.F.R. § 314.70(c)(2), § 314.71 (supplemental applications for changes in labeling must be filed contemporaneously with making such changes and are subject to the same approval procedures in effect for new drug applications). FDA made just such a determination here. *See* Pet. 5-6.

so that this case can be considered in conjunction with *Cipollone*.)

Respondent, however, misses the pivotal point that this is a case presenting a *conflict* between federal and state requirements, not a case raising the issue whether Congress expressly preempted state law or did so implicitly by "occupying the field" of drug labeling regulation. The presence or absence of a federal remedy simply is not an issue. Here, the standards of conduct imposed by federal law conflict with those imposed by state law. In light of this conflict, the Supremacy Clause bars the state from enforcing its standards of conduct, and the absence of a remedy, federal or state, has no legal significance.

Because respondent ignores this straightforward analysis, her reliance on cases such as *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), is misplaced. In *Silkwood*, unlike here, federal and state law were deemed to be complementary rather than contradictory. The Court noted that even though federal law occupied the field of nuclear safety regulation, such "field preemption" did not preclude an award of punitive damages against an operator of a nuclear fuel facility that released radiation in violation of federal regulations *and* standards imposed by state tort law. Under those circumstances, tort law served to complement federal safety regulations by allowing private plaintiffs to recover punitive damages for breaches of the federal law. The question, therefore, was whether the federal law was nevertheless so comprehensive as to preclude the state remedy, and the Court held that, in part because of the absence of a federal private remedy, it was not.

In this case, unlike *Silkwood*, respondent does not seek redress under state tort law for conduct simultaneously deemed unlawful under federal regulations. To the contrary, the warning she would require was specifically barred by federal law. In a context such as this, the presence or absence of federal remedies has no relevance, because the state law duty, the violation of which might otherwise give rise to the tort remedy, is unenforceable under the Supremacy Clause.

Finally, we respectfully suggest that Congress, and the FDA, know quite well that *salus populi suprema lex*. *See* Brief in Opp. 11 (citing Cicero, *De Legibus*, III). Together they created a comprehensive federal scheme for the regulation of prescription drugs, including the drug involved in this case. The federal regulatory scheme requires FDA to balance risks and benefits and to consider carefully what must appear on each drug's "label." In order to protect the safety of the public in general, FDA struck what it perceived to be the appropriate balance in this case, and petitioner complied with FDA's directive. A hodgepodge of labeling requirements imposed by state law, over the objection of the federal regulators, would not (in the judgment of Congress) contribute to the "salus populi." More importantly, when state law and

federal law conflict, the Constitution makes federal law the *suprema lex.*

Respectfully submitted,

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